REMARKS/ARGUMENTS

Status of the Claims

Claims 4 and 12-22 have been canceled without prejudice or disclaimer of the subject matter claimed therein. These claims were withdrawn from consideration in the Office Action for being drawn to non-elected subject matter. Applicants expressly reserve the right to file continuing applications or take such other appropriate measures deemed necessary to protect the subject matter of the canceled claims.

Claims 1 and 8 have been amended due to the restriction requirement. Parts (a) and (b) of these claims have been deleted and parts (c), (d), (f), and (h) have been amended to remove the recitation of non-elected subject matter to overcome an objection set forth in the Office Action. In addition, parts (e) and (g) have been deleted in the interest of furthering prosecution of the instant application

Specifically, parts (c) and (f) of claims 1 and 8 have been amended to remove the recitation of SEQ ID NOs: 3, 5, and 7 therein. Similarly, part (d) has been amended to remove the recitation of SEQ ID NOs: 4, 6, and 8 therein. In addition, part (f) has been further amended to replace "OAR" with the recitation --3-oxoacyl-[acyl carrier protein] reductase (OAR)--. This replacement was necessitated by the cancellation of original part (a), which contained this recitation. Finally, part (h) has been amended to remove the recitation of original parts (a), (b), (e), and (g) therein, to remove the recitation "wherein said nucleotide sequence is capable of antisense suppression of OAR expression in a cell" and to insert --fully-- immediately before "complementary" as suggested by the Examiner. As amended, claims 1 and 8 include parts (a)-(d) which correspond to parts (c), (d), (f), and (h) of original claims 1 and 8. These amendments to claims 1 and 8 were made without prejudice or disclaimer of the deleted subject matter. Applicants expressly reserve the right to file continuing applications or take such other appropriate measures deemed necessary to protect the subject matter deleted from these claims.

Claims 1 and 8 have been additionally amended to point out more distinctly Applicants' claimed invention. Part (f) has been amended to recite "a nucleotide sequence having at least 95%

sequence identity . . . ." Support for this amendment to claims 1 and 8 can be found in the specification, particularly on page 7 at lines 3-16.

No new matter has been added by way of amendment of the claims.

Claims 1-3 and 5-11 are pending.

Reexamination and reconsideration of the application as amended are respectfully requested in view of the following remarks.

SEQ ID NOS: 1 and 2 Are Free of the Prior Art

Applicants respectfully acknowledge that the Examiner has determined that SEQ ID NOs: 1 and 2 are deemed free of the prior art as is indicated on page 7 of the Office Action.

The Claim Objections Should Be Withdrawn

Claims 1 and 8 have been objected to for reciting non-elected inventions, specifically parts (a), (b), (h), and SEQ ID NOS: 3, 5, and 7. As described above, Applicants have amended claims 1 and 8 to remove the recitation of non-elected inventions.

In view of the amendments, it is submitted that the objections to claims 1 and 8 should be withdrawn.

The Rejections of the Claims Under 35 U.S.C. § 112, Second Paragraph, Should Be Withdrawn

Claims 1-3 and 5-11 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims 1 and 8 have been amended. This rejection is respectfully traversed.

The Office Action indicates that, in part (g) of claims 1 and 8, it is unclear what conditions are "low stringency" as what constitutes "low stringency" to one skilled in the art may be moderate stringency to another. The Office Action suggests that the hybridization conditions be specified.

The instant specification, however, sets forth with particularity on page 11 (lines 18-21) what Applicants intend by low stringency. Thus, the claims are not unclear for reciting "low stringency" therein.

The Office Action also indicates that part (h) of claims 1 and 8 are currently not being examined as being drawn to non-elected subject matter but that complementary sequences may be examined in the instant specification if the claims are amended to omit the antisense recitation. The Office Action suggests that, if Applicants wish to include complementary sequences for examination, the word "fully" should be inserted before "complementary" to avoid the claim reading on a two-base sequence.

In the interest of furthering prosecution Applicants have amended claims 1 and 8 to delete part (g) and have amended part (h) of these claims to delete the antisense recitation and to insert --fully--immediately before complementary as recommended in the Office Action. Accordingly, amended claims 1 and 8 and their respective dependent claims are not indefinite.

In view of the amendments and remarks, it is submitted that the rejections under 35 U.S.C. § 112, second paragraph, should be withdrawn.

The Rejections of the Claims Under 35 U.S.C. § 112, First Paragraph, Should Be Withdrawn

Claims 1-3 and 5-11 have been rejected under 35 U.S.C. § 112, first paragraph. Claims 1 and 8 have been amended. This rejection is respectfully traversed.

Enablement

Claims 1-3 and 5-11 have been rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Office Action indicates that the specification, while being enabling for SEQ ID NO: 1 or a polynucleotide sequence encoding SEQ ID NO: 2, does not provide reasonable enablement for 15 contiguous bases of SEQ ID NO: 1, sequences having 85% sequence identity to SEQ ID NO: 1 having OAR activity, and 20 nucleotides that hybridize under low stringency with SEQ ID NO: 1 having OAR activity. The Office Action asserts that neither the specification nor the prior art provide guidance on catalytic domains and regions which would tolerate deletions, additions and/or substitutions, and thus one of skill in the art would not know

which 15 or 20-mer would encode polypeptides having OAR activity without undue experimentation. The Office Action further indicates that SEQ ID NO: 1 has a poly-A tail of 43 A's and would hybridize to the complementary sequence of any sequence having a poly-A tail. The Office Action concludes that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claims.

The Office Action asserts that Applicants have provided no working examples of any sequences having less than 100% sequence identity with SEQ ID NO: 1. The Examiner is respectfully reminded that the instant application discloses, not one nucleotide sequence encoding an OAR, but rather four nucleotide sequences encoding OARs. As indicated in the instant specification on page 40, SEQ ID NOs: 1 and 3 encode the maize OARs having the amino acid sequences set forth in SEQ ID NOs: 2 and 4, respectively, and SEQ ID NOs: 5 and 7 encode the soybean OARs having the amino acid sequences set forth in SEQ ID NOs: 6 and 8, respectively. The Examiner is further reminded that all eight of these sequences are set forth in the Sequence Listing. In view of these sequences alone, one of ordinary skill in the art would be able to identify regions of the OAR having the amino acid sequence set forth in SEQ ID NO: 2 that can tolerate deletions, additions and/or substitutions without undue experimentation. Furthermore, while methods for sequence alignments, sequence comparisons, and determining percent sequence identity are within the knowledge of one of ordinary skill in the art, additional guidance for is set forth in the specification on pages 12-17.

As discussed above, claims 1 and 8 have been amended to delete parts (e) and (g). Furthermore, part (f) of these claims has been amended to recite a nucleotide sequence having at least 95% sequence identity to the nucleotide sequence set forth in SEQ ID NO: 1.

In contrast to the conclusions of the Office Action, the specification provides sufficient guidance to make and identify the isolated nucleotide molecules encompassed by the claims. In particular, Applicants have provided the nucleotide sequence of SEQ ID NO: 1. The claimed nucleotide sequences vary from this sequence by structural parameters (*i.e.*, at least 95% sequence identity to SEQ ID NO 1) that can be determined by those of ordinary skill in the art.

While methods for sequence alignments, sequence comparisons, and determining percent sequence identity are within the knowledge of one of ordinary skill in the art, additional guidance for is set forth in the specification on pages 12-17.

Moreover, the nucleotide sequences of the invention encode polypeptides having OAR activity. Such nucleotide sequences include those that are fragments and variants of SEQ ID NO: 1 and that encode biologically functional OARs. Methods for assaying whether the nucleotide sequences encode biologically functional OARs are known in the art and are also provided in the instant specification on page 8 at lines 29-31. Accordingly, based on the guidance in the specification, one of ordinary skill in the art would be able to determine which nucleotide sequences are encompassed by the present invention.

The Federal Circuit has repeatedly stated that enablement is not precluded by the necessity for some experimentation, so long as the experimentation needed to practice the invention is not undue. *In re Wands* 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988). Furthermore, a considerable amount of experimentation is permissible, if it is merely routine, or if the specification provides a reasonable amount of guidance in which the experimentation should proceed. *Id.*

Applicants stress that when evaluating the quantity of experimentation required, the court looks to the amount of experimentation required to practice a single embodiment of the invention, rather than the amount required to practice every embodiment of the invention. For example, in *Wands*, the claims at issue were drawn to immunoassay methods using any monoclonal antibody having a binding affinity for HbsAg of at least 10-9 M. The USPTO had taken the position that the claim was not enabled as it would take undue experimentation to make the monoclonal antibodies required for the assay. The Federal Circuit reversed, and held that the claims were enabled, as the amount of experimentation required to isolate monoclonal antibodies and screen for those having the correct affinity was not undue. *Id.* Clearly, the Federal Circuit did not contemplate that every antibody useful in the methods of the claim must be identified. Rather, the court considered the amount of experimentation required to identify one or a few monoclonal antibodies having the required affinity.

In the instant case, the quantity of experimentation required to practice the invention amounts to two steps: (*i*) identifying a nucleotide sequence that comprises at least 95% sequence identity to SEQ ID NO: 1, and (*ii*) assaying the protein encoded thereby for OAR activity. Thus, ample guidance is provided to allow one of skill in the art to identify additional nucleotide sequences encompassed by claims 1 and 8 and their respective dependent claims. Consequently, contrary to the conclusions of the Office Action, the quantity of experimentation necessary and the amount of guidance presented in the specification is sufficient to enable Applicants' claimed invention. Accordingly, Applicants submit that claims 1-3 and 5-11 are enabled under 35 U.S.C. §112, first paragraph.

In view of the amendments and above remarks, it is apparent that those of skill in the art would be able to practice the present claims without undue experimentation. Accordingly, the enablement rejection of claims 1-3 and 5-11 should be withdrawn.

Written Description

Claims 1-3 and 5-11 have been rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. The Office Action indicates the claims reciting at least 85% sequence identity lack adequate written description because Applicants do not disclose a representative number of species as encompassed by these claims. The Office Action further indicates that the claims encompass mutants and allelic variants and thus imply structural variants exist in nature, yet no structural variant has been disclosed. The Office Action indicates that the claims also encompass OAR polypeptides from other species. The Office Action asserts that the is implication is that there is a gene and a protein other than that disclosed which exists in nature but that the structure thereof is not known. The Office Action further asserts that there are insufficient identifying characteristics to allow one skilled in the art to predictably determine mutants, allelic variants, and OAR polypeptides from other plants and organisms.

Again, the Examiner is respectfully reminded that the instant application discloses, not one nucleotide sequence encoding an OAR, but rather four nucleotide sequences encoding OARs. As discussed in detail above, the instant application discloses the nucleotide and amino

acid sequences for two maize OARs and two soybean OARs. Also as discussed above, claims 1 and 8 have been amended to delete parts (e) and (g), and part (f) of these claims has been amended to recite a nucleotide sequence having at least 95% sequence identity to the nucleotide sequence set forth in SEQ ID NO: 1.

As amended, claims 1 and 8 recite—as *Regents of the University of California v. Eli Lilly and Co.*, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997) requires—both the functional and structural features of the claimed isolated nucleotide sequences. As amended, claims 1 and 8 recite that the fragment and variant nucleotide sequences encode polypeptides having OAR activity or are the full complements of such nucleotide sequences. The specification provides adequate description of the subject matter of the amended claims and their respective dependent claims so as to reasonably convey to one skilled in the relevant art that Applicants had possession of the invention as claimed. In particular, the specification discloses on pages 6-9 that the invention encompasses fragments and variants of the disclosed nucleotide sequence, wherein such fragments and variants encode polypeptides that retain OAR activity. Accordingly, the subject matter of amended claims 1 and 8 and their dependent claims is adequately described in the instant specification so as to reasonably convey to one of ordinary skill in the relevant art that, at the time of the invention, Applicants had possession of the claimed invention. The written description requirement of 35 U.S.C. §112, first paragraph, has been satisfied.

In summary, in view of the amendments and above remarks, claims 1-3 and 5-11 satisfy the written description requirement of 35 U.S.C. §112, first paragraph. Accordingly, the written description rejection of claims 1-3 and 5-11 should be withdrawn.

The Rejection of the Claims Under 35 U.S.C. § 102(e) Should Be Withdrawn

Claims 1-3 and 5-9 have been rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Pat. No. 6,346,395. Claims 1 and 8 have been amended. This rejection is respectfully traversed.

The Office Action asserts that U.S. Pat. No. 6,346,395 discloses a nucleic acid molecule comprising at least 20 nucleotides which hybridizes under low stringency conditions to SEQ ID NO: 1 and encodes a polypeptide having OAR activity. The Office Action indicates that U.S. Pat. No. 6,346,395 teaches the expression of OAR in an angiosperm plant.

Claims 1 and 8 have been amended to delete part (g), which had been directed to nucleotide sequences that hybridize to at least one of the exemplified nucleotide sequences of the invention. Applicants submit that, in view of the amendments to claims 1 and 8, claims 1-3 and 5-9 are not anticipated by U.S. Pat. No. 6,346,395.

In view of the amendments and remarks, it is submitted that the rejection of claims 1-3 and 5-9 under 35 U.S.C. § 102(e) should be withdrawn.

The Rejection of the Claims Under 35 U.S.C. § 103(a) Should Be Withdrawn

Claims 1-3 and 5-11 have been rejected under 35 U.S.C. § 103(a) as being unpatenable over U.S. Pat. No. 6,346,395 as applied to claims 1-3 and 5-9 above and in further view of U.S. Pat. No. 4,956,282. Claims 1 and 8 have been amended. This rejection is respectfully traversed.

The Office Action refers to the teachings of U.S. Pat. No. 6,346,395 as discussed above concerning the claims rejections under 35 U.S.C. § 102(e). The Office Action indicates that U.S. Pat. No. 6,346,395 does not teach the specific plants of claim 9 and the transgenic seed in claim 10. The Office Action indicates that U.S. Pat. No. 4,956,282 teaches the expression of heterologous proteins in plants as listed in claim 9 and transgenic seed. The Office Action concludes that it would have been prima facie obvious to one skilled in the art at the time the invention was made to substitute the heterologous protein of U.S. Pat. No. 4,956,282 with the OAR protein of U.S. Pat. No. 6,346,395 and to express OAR in plants and seeds for the purpose of obtaining OAR in any desired host plant such as corn, soybean, etc.

Claims 1 and 8 have been amended to delete part (g), which had been directed to nucleotide sequences that hybridize to at least one of the exemplified nucleotide sequences of the invention. Applicants submit that, as amended, these claims, and their respective dependent

claims do not encompass the nucleic acid molecule of U.S. Pat. No. 6,346,395 that encodes a polypeptide having OAR activity. Furthermore, U.S. Pat. Nos. 6,346,395 and 4,956,282, whether taken alone or in combination, neither teach nor render obvious the nucleotide sequences of amended claims 1 and 8. Accordingly, in view of the amendments to claims 1 and 8, claims 1-3 and 5-11 are not obvious in view of the cited patents.

In view of the amendments and remarks, it is submitted that the rejection of claims 1-3 and 5-11 under 35 U.S.C. § 103(a) should be withdrawn.

CONCLUSION

In view of the above amendments and remarks, Applicants submit that the objections to the claims and the rejections of the claims under 35 U.S.C. §§ 102, 103, and 112 are overcome. Applicants respectfully submit that this application is now in condition for allowance. Early notice to this effect is solicited.

If in the opinion of the Examiner a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required

therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being facsimile transmitted to Examiner Phuong T. Bui, Crystal Mall 1, Art Unit 1638, the US Patent and Trademark Office at facsimile number (703) 872-9306 on the date shown below.

Marilyn Muñoz

April 6, 2004
Date